



Dr

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February 07, 2012

Examiner Jeanette M. Lieb
Commissioner for Patents
PO Box 1450
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RE: Application Number: 10/580,904
Title: Compositions and Methods Comprising Collagen
Filing Date 07/29/2008
Inventor Nels J. Lauritzen
Examiner Jeanette M. Lieb

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The following is the response to the basis for the rejections in the most recently supplied office action.

1. Claims 21-24, 27 and 28 under 35 U.S.C. 102 (b) as being anticipated by Shadwick et. Al. (Structure and Function of tuna tail tendons, Comparative Biochemistry and Physiology Part A (133) 1109-1125, 2002).

Shadwick did not foresee, predict, observe or apply the salient work required to 'anticipate' the work disclosed in the subject patent application or provide adequate grounds for useful products thereof.

- The tuna tendon,...although capable of similar working function to that of mammals in many cases exhibits reduced elasticity & breaking strength. Further attempts at isolation of collagen by Shadwick's methods result in inferior collagen fibers resembling particulate structures not useful as medical devices scaffolds.
- The particulate fibers resulting from Shadwick's procedure, when reconstituted, are brittle and inflexible thereby indicating that our invention is surprisingly differentiated from anything foreseen or predicted by Shadwick.
- Shadwick's isolation & recovery procedure resulted in a structure similar to Type I Collagen, having some mammalian collagen characteristics but lacking fibrillar structure and the temperature stability ('shrink/melt temperature') required for products of utility in various medical devices such as wound care matrices, neural tube grafts and structural cable for use as bladder sling & spinal repair.
- Shadwick does not address isolated or purified collagen in a reconstituted form and does not predict reconstituted forms such as scaffold, cable, tube, composites